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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,182	08/07/2003	Christopher A. Thierfelder	AMS-161	1760

7590 10/15/2007

Attention: Jeffrey J. Hohenshell
AMS Research Corporation
10700 Bren Road West
Minnetonka, MN 55343

EXAMINER
GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
10/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,182	THIERFELDER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 7/30/2007.

2. In the reply, the Applicant amended claim 13.

3. Thus, claims 13-16 remain pending for examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 recites the limitation that the substance for resisting fibrous occlusions comprises poly(GVGVP). The specification only describes using poly(GVGVP) as a coating on the catheter (see paragraphs 10, 13, 54-55). The specification does not recite poly(GVGVP) as acting as a substance that is deliver to the ports for resisting the fibrous occlusion of the drug delivery ports. The only substance that the Applicant has disclosed in the originally filed specification that qualifies as a substance that is deliver to the ports for resisting the fibrous occlusion of the drug delivery ports is PLGA microspheres with dexamethasone (see paragraph 56). Thus, for purposes of examination the Examiner has interpreted claims 13-14 to invoke

112(6th) paragraph using means-for language having a drug delivery path preservation means-for delivering a substance to the ports that resists fibrous occlusions to be PLGA microspheres with dexamethasone. Claim 14 needs to be corrected as appropriate to comply with the written description requirement.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites "wherein the substance for resisting fibrous occlusions in the drug delivery ports." The claim limitations to not make sense to the Examiner nor recite subject matter not already recited in claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil, Jr. (5041107). Heil, Jr. discloses an implantable drug delivery system (10) having a storage area (14; col 5, lns 29-38) for storing a drug; a metering for metering a predetermined, effective amount of the drug though a drive electrode (22), a power

source (12) and oppositely charged return electrode (26) (col 2, lns 8-56; col 4, lns 16-30); a delivery means for delivering an effective amount of drug comprising a catheter (14) having a longitudinal axis (Fig 1) and having a plurality of drug delivery ports (22, 32, 44) being a plurality of slits (22, 32, 44) that are movable between an open position to delivery the drug to the patient and a closed position (col 3, lns 54-56; col 4, lns 7-9; col 4, lns 16-30); a drug delivery path preservation means comprising a substance for resisting the fibrous occlusion proximate and in the drug delivery ports and wherein the substance is in the drug delivery ports (col 4, lns 36-46, col 4, lns 58-63; wherein the Examiner notes that the portion of the catheter body (36, 38) whereby the film or membrane (34) is tightly conformed over and attached is proximate and structured over the drug delivery port and the film or membrane (34) is a substance that resists formation of fibrous occlusions, such as blood clots via fibrinogen and thrombin (col 6, lns 40-43, lns 58-63).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise et al (5752930) in view of Whitehurst et al (6970741). Rise et al discloses an implantable drug delivery system comprising: a storage area (19; Fig 4) for storing a drug, a meter for metering a predetermined, effective amount of the drug; delivery

means for (Summary, col 2, lns 66-col 4 lns 34) delivering the effective amount of the drug to a patient to treat a disorder, the delivery means comprising: a catheter having a plurality of drug delivery ports (172), the drug delivery ports being movable between an open position to deliver the drug to the patient, and a closed position (172, Summary). However, Rise et al does not expressly disclose drug delivery path preservation means for delivering a substance to the ports for resisting fibrous occlusion of the drug delivery ports, the drug delivery preservation means being proximate the drug delivery ports.

12. Whitehurst et al teaches that it is known to have drug delivery path preservation means for delivering a substance to the ports for resisting fibrous occlusion of the drug delivery ports (Summary, col 4, lns 28-34; col 11, lns 6-17), the drug delivery preservation means being proximate the drug delivery ports (Fig 3b, 4) for the purpose of suppression of immune rejection that leads to an immune attack, fibrous occlusion of the device resulting in loss of function. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable drug delivery device as taught by Rise et al with the drug delivery path preservation means as taught by Whitehurst et al for the purpose of suppression of immune rejection that leads to an immune attack, fibrous occlusion of the device resulting in loss of function.

13. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise et al (5752930) in view of Stokes et al (6567705). Rise et al discloses an implantable drug delivery system comprising: a storage area (19; Fig 4) for storing a

drug, a meter for metering a predetermined, effective amount of the drug; delivery means for (Summary, col 2, lns 66-col 4 lns 34) delivering the effective amount of the drug to a patient to treat a disorder, the delivery means comprising: a catheter having a plurality of drug delivery ports (172), the drug delivery ports being movable between an open position to deliver the drug to the patient, and a closed position (172, Summary). However, Rise et al does not expressly disclose drug delivery path preservation means for delivering a substance to the ports for resisting fibrous occlusion of the drug delivery ports, the drug delivery preservation means being proximate the drug delivery ports.

14. Stokes et al teaches that it is known to have drug delivery path preservation means for delivering a substance to the ports for resisting fibrous occlusion of the drug delivery ports (col 8, lns 49-col 9, ln 10; Fig 4), the drug delivery preservation means being proximate the drug delivery ports (col 8, lns 49-col 9, ln 10; Fig 4) for the purpose of controlling inflammation and the resulting fibrous encapsulation of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable drug delivery device as taught by Rise et al with the drug delivery path preservation means as taught by Stokes et al for the purpose of controlling inflammation and the resulting fibrous encapsulation of the device.

Response to Arguments

15. Applicant's arguments with respect to claims 13-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 2004/0054389; 2004/0158232; 5609629; 6443949; 6584363.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER